

# PATENT COOPERATION TREATY

## PCT NOTIFICATION OF ELECTION (PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner  
US Department of Commerce  
United States Patent and Trademark  
Office, PCT  
2011 South Clark Place Room  
CP2/5C24  
Arlington, VA 22202  
ETATS-UNIS D'AMERIQUE  
in its capacity as elected Office

|   |   |
|---|---|
| <b>Date of mailing (day/month/year)</b><br>22 January 2002 (22.01.02)       | <b>Applicant's or agent's file reference</b><br>1585-0002       |
| <b>International application No.</b><br>PCT/US01/16696                      | <b>Priority date (day/month/year)</b><br>31 May 2000 (31.05.00) |
| <b>International filing date (day/month/year)</b><br>23 May 2001 (23.05.01) |   |
| <b>Applicant</b><br>BRYDEN, Wayne, A. et al                                 |   |

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

13 December 2001 (13.12.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

|  |   |
|--|---|
| <b>The International Bureau of WIPO</b><br>34, chemin des Colombettes<br>1211 Geneva 20, Switzerland<br><br>Facsimile No.: (41-22) 740.14.35 | <b>Authorized officer</b><br><br><p style="text-align: center;">R. Forax</p> Telephone No.: (41-22) 338.83.38 |
|--|---|

10/031036 #3  
(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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International Bureau



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PCT

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WO 01/092872 A3

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(21) International Application Number: PCT/US01/16696

(22) International Filing Date: 23 May 2001 (23.05.2001)

(25) Filing Language: English

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(30) Priority Data:  
60/207,964 31 May 2000 (31.05.2000) US

(71) Applicant (for all designated States except US): THE  
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(72) Inventors; and

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kins Road, Laurel, MD 20723-6099 (US).

(81) Designated States (national): AE, AG, AL, AM, AT, AU,  
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,  
CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM,  
HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK,  
LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX,  
MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL,  
TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM,  
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian  
patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European  
patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,  
IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF,  
CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:  
— with international search report

(88) Date of publication of the international search report:  
30 January 2003

For two-letter codes and other abbreviations, refer to the "Guid-  
ance Notes on Codes and Abbreviations" appearing at the begin-  
ning of each regular issue of the PCT Gazette.

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WO 01/092872 A3

(54) Title: METHODS FOR USING MASS SPECTROMETRY TO IDENTIFY AND CLASSIFY FILAMENTOUS FUNGI,  
YEASTS, MOLDS AND POLLEN

(57) Abstract: A method for the identification and classification of filamentous fungi, yeasts, molds, toxins produced by fungi, and pollen in air environmental and biological samples using genus, species and strain specific biomarkers is provided. The biomarkers can be generated using mass spectrometers and particularly by matrix assisted laser desorption ionization time-of-flight mass spec-  
trometry (MALDI-TOF-MS) analyses of filamentous fungi, yeasts, molds, toxins produced by fungi, and pollen.

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT PCT

(PCT Article 36 and Rule 70)

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|   |   |  |
|---|---|--|
| Applicant's or agent's file reference<br>1585-0002  | <b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |  |
| International application No.<br>PCT/US 01/ 16696   | International filing date (day/month/year)<br>23/05/2001  | Priority date (day/month/year)<br>31/05/2000 |
| International Patent Classification (IPC) or national classification and IPC<br>G01N33/00 |   |  |
| Applicant<br>THE JOHNS HOPKINS UNIVERSITY et al.  |   |  |

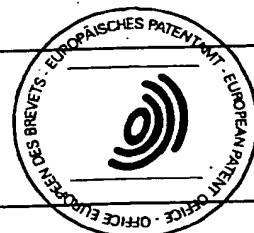
1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This **REPORT** consists of a total of 2 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consists of a total of \_\_\_\_\_ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

|   |  |
|---|--|
| Date of submission of the demand<br>13/12/2001  | Date of completion of this report<br>27/05/2002            |
| Name and mailing address of the IPEA/<br> European Patent Office<br>D-80298 Munich<br>Tel. (+49-89) 2399-0, Tx: 523656 epmu d<br>Fax: (+49-89) 2399-4465 | Authorized officer<br>BRENNAN J<br>Tel. (+49-89) 2399 2828 |



**I. Basis of the report**

The basis of this international preliminary examination is the application as originally filed.

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The question of whether the claimed invention appears to be novel, to involve an inventive step, or to be industrially applicable has not been the subject of the international preliminary examination in respect of the claims which have not been searched (Article 17(2)(a) or (3) and Rule 66.1(e) PCT); see also international search report).

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability**

To the extent that the international preliminary examination has been carried out (see item III above), the following is pointed out:

In light of the documents cited in the international search report, it is considered that the invention as defined in at least some of the claims, which have been the subject of an international search report, does not appear to meet the criteria mentioned in Article 33(1) PCT, i.e. does not appear to be novel and/or to involve an inventive step (see international search report, in particular the documents cited X and/or Y and corresponding claim references).

JUL 9 2002

## INTERNATIONAL SEARCH REPORT

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(PCT Article 18 and Rules 43 and 44)

|   |   |  |
|---|---|--|
| Applicant's or agent's file reference<br><b>1585-0002</b> | <b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below. |  |
| International application No.<br><b>PCT/US 01/ 16696</b>  | International filing date (day/month/year)<br><b>23/05/2001</b>   | (Earliest) Priority Date (day/month/year)<br><b>31/05/2000</b> |
| Applicant<br><b>THE JOHNS HOPKINS UNIVERSITY et al.</b>   |   |  |

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

## 1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures.

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 206

Continuation of Box 3.

Claims Nos.: 22-25

Present claims 22-25 relate to a biomarker library defined by reference to a desirable characteristic or property, namely comprising genus, species or strain specific biomarkers for known bioorganic compounds generated by the methods of claim 1 or 6.

The claims cover all biomarker libraries having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for no such biomarker library. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has not been carried out for those claims.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:
- 1-21
2. This communication is not the international search report which will be established according to Article 18 and Rule 43.
3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.
4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |
|------------|--|-----------------------|
| X          | WELHAM K J ET AL: "Matrix-assisted laser-desorption/ionization time-of-flight mass spectrometry and its application to the analysis of fungal spores."<br>PHARMACY AND PHARMACOLOGY COMMUNICATIONS, vol. 6, no. 3, March 2000 (2000-03), pages 107-111, XP001052985<br>ISSN: 1460-8081<br>the whole document | 1-21                  |
| X          | WELHAM K J ET AL: "Characterization of fungal spores by laser desorption/ionization time-of-flight mass spectrometry."<br>RAPID COMMUNICATIONS IN MASS SPECTROMETRY., vol. 14, no. 5, 29 February 2000 (2000-02-29), pages 307-310, XP001052924<br>ISSN: 0951-4198<br>the whole document                     | 1-21                  |

☒ Further documents are listed in the continuation of box C.

☐ Patent family members are listed in annex.

° Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*G\* document member of the same patent family

Annex to Form PCT/ISA/206  
COMMUNICATION RELATING TO THE RESULTS  
OF THE PARTIAL INTERNATIONAL SEARCH

International Application No  
PCT/US 01/16696

| C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT |  |                       |
|--|--|-----------------------|
| Category *   | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |
| P, X   | <p>LI TZU-YING ET AL: "Characterization of Aspergillus spores by matrix-assisted laser desorption/ionization time-of-flight mass spectrometry."<br/> RAPID COMMUNICATIONS IN MASS SPECTROMETRY, vol. 14, no. 24,<br/> 23 November 2000 (2000-11-23), pages 2393-2400, XP001052923<br/> ISSN: 0951-4198<br/> the whole document</p> | 1-20                  |
| T  | <p>AMIRI-ELIASI B ET AL: "Characterization of protein biomarkers desorbed by MALDI from whole fungal cells."<br/> ANALYTICAL CHEMISTRY, (2001 NOV 1) 73 (21) 5228-31.,<br/> - November 2001 (2001-11) XP002187835<br/> the whole document</p>  |                       |



## PATENT COOPERATION TREATY

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## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

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|   |   |  |
|---|---|--|
| Applicant's or agent's file reference<br><b>1585-0002</b> | <b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below. |  |
| International application No.<br><b>PCT/US 01/ 16696</b>  | International filing date (day/month/year)<br><b>23/05/2001</b>   | (Earliest) Priority Date (day/month/year)<br><b>31/05/2000</b> |
| Applicant<br><b>THE JOHNS HOPKINS UNIVERSITY et al.</b>   |   |  |

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.  
☒ It is also accompanied by a copy of each prior art document cited in this report.

## 1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures.

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 01/16696

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 22-25  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:  
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-21 partially

A method for generating biomarkers specific for a known genus, species, or strain of bioorganic compound selected from the group consisting of filamentous fungi, yeasts, molds, toxins of fungi.

2. Claims: 1-21 partially

A method for generating biomarkers specific for a known genus, species, or strain of pollen.

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 22-25

Present claims 22-25 relate to a biomarker library defined by reference to a desirable characteristic or property, namely comprising genus, species or strain specific biomarkers for known bioorganic compounds generated by the methods of claim 1 or 6.

The claims cover all biomarker libraries having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for no such biomarker library. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has not been carried out for those claims.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/16696

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12Q1/02 C12Q1/04

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C12Q G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, BIOSIS, MEDLINE, CHEM ABS Data, EMBASE, SCISEARCH, EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No. |
|------------|---|-----------------------|
| X          | <p>WELHAM K J ET AL: "Matrix-assisted laser-desorption/ionization time-of-flight mass spectrometry and its application to the analysis of fungal spores."</p> <p>PHARMACY AND PHARMACOLOGY COMMUNICATIONS, vol. 6, no. 3, March 2000 (2000-03), pages 107-111, XP001052985</p> <p>ISSN: 1460-8081</p> <p>the whole document</p> <p style="text-align: center;">---<br/>-/--</p> | 1-21                  |



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

## \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*G\* document member of the same patent family

Date of the actual completion of the international search

24 June 2002

Date of mailing of the international search report

23. 07. 2002

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
 NL - 2280 HV Rijswijk  
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
 Fax: (+31-70) 340-3016

Authorized officer

Niemann, F

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/16696

| C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT |   |                       |
|--|---|-----------------------|
| Category *   | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No. |
| X  | <p>WELHAM K J ET AL: "Characterization of fungal spores by laser desorption/ionization time-of-flight mass spectrometry."<br/>RAPID COMMUNICATIONS IN MASS SPECTROMETRY.,<br/>vol. 14, no. 5,<br/>29 February 2000 (2000-02-29), pages 307-310, XP001052924<br/>ISSN: 0951-4198<br/>the whole document</p>                                      | 1-21                  |
| P,X  | <p>LI TZU-YING ET AL: "Characterization of Aspergillus spores by matrix-assisted laser desorption/ionization time-of-flight mass spectrometry."<br/>RAPID COMMUNICATIONS IN MASS SPECTROMETRY,<br/>vol. 14, no. 24,<br/>23 November 2000 (2000-11-23), pages 2393-2400, XP001052923<br/>ISSN: 0951-4198<br/>the whole document</p>              | 1-20                  |
| A  | <p>DELUCA S J ET AL: "Pyrolysis-mass spectrometry methodology applied to southeast Asian environmental samples for differentiating digested and undigested pollens."<br/>ANALYTICAL CHEMISTRY. UNITED STATES OCT 1986,<br/>vol. 58, no. 12, October 1986 (1986-10), pages 2439-2442, XP002203274<br/>ISSN: 0003-2700<br/>the whole document</p> |                       |
| T  | <p>AMIRI-ELIASI B ET AL: "Characterization of protein biomarkers desorbed by MALDI from whole fungal cells."<br/>ANALYTICAL CHEMISTRY, (2001 NOV 1) 73 (21) 5228-31.,<br/>- November 2001 (2001-11) XP002187835<br/>the whole document</p>  |                       |